

Serial No. 10/672,009

Dkt.: P0022022.00

Filing Date: September 26, 2003

Title: SURGICAL CONNECTION APPARATUS AND METHODS

REMARKS

Reconsideration and withdrawal of the rejections of claims 1-17 and 19-33, in view of the remarks presented herein, is respectfully requested.

Claims 10, 17, 22, and 28 have been amended. The amendments to the claims are fully supported by the Specification as filed. No new matter is believed to be introduced by way of this amendment.

The 35 U.S.C. § 102(e) rejection of the claims

The Examiner rejected claims 1, 2, 6/1, 6/2, 7/1, 7/2, 8, 14/8, 15/8, 16/8, 17-28 and 30-33 under 35 U.S.C. § 102(e) as being anticipated by Edoga *et. al.* ("Edoga" U.S. Patent No. 7,335,212). As this rejection may be maintained with respect to the pending claims, it is respectfully traversed.

Independent Claim 1

In response to the Examiner's statement at Page 2 of the Office Action that "Applicant argues that the clip 134 of Edoga is not a shape memory self-closing clip...nowhere in [the claims] ... claimed a shape memory self-closing clip", Applicants respectfully note that the arguments made in the Response and Amendment of January 29, 2009 were in response to the Examiner's own statement in the Office Action of October 29, 2008 that "Edoga discloses a plurality of shape memory self closing clips". Applicants maintain that Claim 1 provides in part, "a plurality of self-closing clips". The Examiner has now set forth that while Edoga fails to disclose shape memory material, wire segment 134 formed into a clip 158 requires no additional structure to keep the clip 158 from closing and is thus "self-closing" as claimed. Applicants respectfully disagree. From the very words recited by the Examiner and disclosed in Edoga, 'wire segment 134 is *formed*', it is readily apparent that the clip *does* require additional structure in order to close, thus it is not self-closing. Straight wire segments 134 slide within passage 132 and through hooked staple guides 140. Edoga discloses "movement of the staple firing trigger 108 will cause the staple drivers 138 to engage the straight wire segments 134 and displace the straight wire segments into hooked staple guides 140 to form the circular staples" Col. 4 line

65 – Col. 5 line 1; see also Col. 6 lines 63-67. In other words, straight wire segments require some other structure (e.g. staple guides 140) in order to be “formed into ring-shaped staples” Col. 1 line 65. Applicants maintain that Edoga fails to disclose self-closing clips as claimed.

Furthermore, Applicants maintain that the wires 134 of Edoga are not ejectable independently of the staple guides 140 since the wires 134 are ejected out of the staple guides 140. The Examiner asserts that since the wire segments 134 are not fixedly attached to the staple guides, the staples are movable independently of the guides. However, claim 1 discloses in part, “clips ejectable from said support structure independently of said barbs” The very purpose of the staple guide is to guide the wire segment as it exits the guide to form a staple 158. Thus, it is abundantly clear that the staples, while not fixedly attached to the guides upon deployment, are not ejected independently of the guides, rather the staples are ejected *using* the guides.

The claims depending from claim 1 include additional allowable subject matter and are allowable at least by virtue of their dependency from an allowable claim thus requiring no further comment at this time. Therefore, it is respectfully submitted that claim 1 and the claims dependent thereon are not anticipated by Edoga. Withdrawal of the rejection is therefore proper and respectfully requested.

Independent Claim 17

Applicants maintain that the wire segments 134 of Edoga are disclosed as being driven out of hooked staple guides 140 and thus are not separate from and movable independently of the so-called “barbs” since they are moved within the “barbs”. Notwithstanding this assertion, in an effort to expedite prosecution, claim 17 has been amended to recite in part, “a support structure comprising a first plurality of arms and a second plurality of arms...wherein the first plurality of arms and the second plurality of arms are arranged to form a plurality of arm pairs”. This is not disclosed or described in Edoga.

The claims depending from claim 17 include additional allowable subject matter and are allowable at least by virtue of their dependency from an allowable claim thus requiring no further comment at this time. Thus, it is respectfully submitted that claim 17 and the claims dependent

thereon are not anticipated by Edoga. Withdrawal of the rejection is therefore proper and respectfully requested.

Independent Claim 22

In an effort to expedite prosecution, claim 22 has been amended to provide in part, "a support structure comprising a plurality of arm pairs, the plurality of arm pairs comprising a first plurality of arms and a second plurality of arms". The arguments above with respect to claim 17 apply with equal force to claim 22. Edoga does not disclose a plurality of arm pairs. Furthermore, and as discussed above, the so-called "clips", wire segments 134, of Edoga are driven out of the so-called "barbs", staple guides 140, and thus the two elements are not independent of one another.

The claims depending from claim 22 are allowable at least by virtue of their dependency from an allowable claim and include additional allowable subject matter. For example, claim 23 provides in part "wherein said clips comprise shape memory material, have a memory set closed configuration, and move toward said closed configuration when ejected from said support structure." Nowhere in the disclosure of Edoga is disclosed a clip having a memory set closed configuration. Likewise, the Examiner has not alleged that Edoga provides such an element, thus claim 23 is not anticipated by Edoga. Thus, it is respectfully submitted that claim 22 and the claims dependent thereon are not anticipated by Edoga. Withdrawal of the rejection is therefore proper and respectfully requested.

Independent Claim 28

The arguments above with respect to claims 17 and 22 apply with equal force to claim 28 which in an effort to expedite prosecution, has been amended to provide in part, "a support structure comprising a plurality of arm pairs, the plurality of arm pairs comprising a first plurality of arms and a second plurality of arms". As explained above, Edoga does not disclose a plurality of arm pairs. In addition, the so-called "clips", wire segments 134, of Edoga are driven out of the so-called "barbs", staple guides 140, and thus the two elements are not independent of one another.

The claims depending from claim 28 are allowable at least by virtue of their dependency from an allowable and require no further comment at this time. Thus, it is respectfully submitted that claim 28 and the claims dependent thereon are not anticipated by Edoga. Withdrawal of the rejection is therefore proper and respectfully requested.

Independent Claim 33

Claim 33 provides in part, "a plurality of barbs, each coupled to said support structure and having a distal end portion...means for moving said barbs between a first position where said distal end portions are inside said support structure to a second position where said distal end portions extend from said support structure". Furthermore, the Examiner is now alleging that housing 101 is the support structure and that obdurator 118 extends the staple guides 140 between a first position where they extend from the support structure and a second position where they are retracted into the support structure. The Examiner references Fig. 4 to support the notion that staple guides retract into housing 101. However, the distal ends of the staple guides, in each figure of Edoga are depicted as being outside of or distal to the distal end of housing 101 and are not shown or described as being retractable *into* housing 101. Thus Edoga fails to disclose every element as set forth in claim 31.

The claims depending from claim 33 include additional allowable subject matter and are allowable at least by virtue of their dependency from an allowable claim thus requiring no further comment at this time. Thus, it is respectfully submitted that claim 33 and the claims dependent thereon are not anticipated by Edoga. Withdrawal of the rejection is therefore proper and respectfully requested.

The 35 U.S.C. § 103(a)) rejection of the claims

The Examiner rejected claims 1-33 under 35 U.S.C. § 103(a) as being unpatentable over Miller et. al. ("Miller" U.S. Patent No. 6,709,442) in view of Loshakove et. al. ("Loshakove" U.S. Patent App. No. 2004/0087985). As this rejection may be maintained with respect to the pending claims, it is respectfully traversed.

Independent Claim 1

The Examiner alleges that Miller discloses the invention substantially as claimed except for the device further includes a plurality of barbs, each barb being coupled to the support structure and the barbs being separate from the clips, which are ejectable from the support structure independently of the barbs. The Office Action goes on to allege that Loshakove discloses in Figs. 5A-5F an anastomosis device comprising a plurality of pullers 512 for pulling the lips of the incision of the blood vessel into a desired location relative to another lip for effecting anastomosis connection and that it would have been obvious to one of ordinary skill in the art to replace the pivoting arms 172 of Miller with the pullers as disclosed by Loshakove in order to improve the effectiveness and safety of Miller's device. Applicant respectfully traverse and maintain that a *prima facie* case of obviousness has not been met. At the outset, side pullers 512 of Loshakove pull on a target vessel lip when retracted which in turn pulls the lips of the target vessel into the clip device 400 and end vessel pullers 510 are retracted to pull the lips of the graft vessel 502 against the clip device 400. In contrast, Miller's pivot arms 172 grasp or interface with a graft vessel via the corresponding abutments 174. Delivery instrument 170 is described as analogous to an umbrella frame which when collapsed, supports the graft, *suppresses* the flange 162, which is used to anchor the graft 158 to the inside of the aorta wall, and transports it through a prepared opening in the aorta. Col. 10 lines 57-63. As shown in FIG. 14, once deployed, arms 172 extend restoring flange 162 and *supporting it* during attachment. The flange 162 is forced to the diameter of the graft body 160 by pivoting arms 172 and the *flange is retained* via abutments 174 on the pivoting arms. Clearly then, replacing pivot arms 172 with side *pullers* 512 would render Miller inoperable as Miller would no longer comprise a means by which graft vessel flange 162 could be suppressed, supported and retained as it is delivered to and retained against the target vessel. The side pullers 512 are configured to *pull* tissue from a target vessel and nothing in the art cited or in the Office Action suggest or show how pullers 512 could *push* or apply force to graft vessel tissue as disclosed in Miller. Furthermore, the Examiner has not advanced how such a combination or substitution of elements would be carried out or why or how such a combination would increase the safety or efficacy of the Miller device. In contrast, as described above, the Examiner's proposed modification would

render the device of Miller inoperable since no structure would exist to restore the flange and support it during attachment to the aorta wall. In addition, Applicants maintain that Miller does not disclose self-closing clips. The fastener 10 and suture element 236 of Miller are disclosed as coils and suture respectively and do not necessarily 'close' let alone "self-close". For at least the foregoing reasons, Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

The claims depending from claim 1 include additional allowable subject matter and are allowable at least by virtue of their dependency from an allowable claim thus requiring no further comment at this time. Thus, it is respectfully submitted that claim 1 and the claims dependent thereon are not unpatentable over Miller in view of Loshakove. Withdrawal of the rejection is therefore proper and respectfully requested.

Independent Claim 17

The arguments with respect to claim 1 apply with equal force to claim 17 and the claims dependent thereon. Miller does not disclose a plurality of barbs and a plurality of clips let alone the paths associated therewith as set forth in claim 17. Loshakove also does not disclose this combination of elements and no reason to modify Miller to include these features has been provided. Additionally, notwithstanding Applicants' assertions, in an effort to expedite prosecution, claim 17 as amended provides in part a first plurality of arms and a second plurality of arms arranged to form a plurality of arm pairs. This is not disclosed or suggested in either Miller or Loshakove. Withdrawal of the rejection is therefore proper and respectfully requested.

Independent Claim 22

The arguments with respect to claim 1 apply with equal force to claim 22 and the claims dependent thereon. Miller does not disclose a plurality of barbs and a plurality of clips independent of the barbs as set forth in claim 22. Loshakove also does not disclose this combination of elements and as discussed no motivation to modify Miller to include these features has been provided. In contrast, the modification proposed by the Examiner would render the device of Miller inoperable. In addition, notwithstanding Applicants' assertions, in an effort

to expedite prosecution, claim 22 as amended provides in part a plurality of arm pairs comprising a first plurality of arms and a second plurality of arms. This is not disclosed or suggested in either Miller or Loshakove. Withdrawal of the rejection is therefore proper and respectfully requested allowable.

Independent Claim 28

The arguments with respect to claim 1 apply with equal force to claim 28 and the claims dependent thereon. Miller does not disclose a plurality of barbs and a plurality of clips independent of the barbs as set forth in claim 28. Loshakove also does not disclose this combination of elements and no reason to modify Miller to include these features has been provided. In addition, notwithstanding Applicants' assertions, in an effort to expedite prosecution, claim 28 as amended provides in part a plurality of arm pairs comprising a first plurality of arms and a second plurality of arms. This is not disclosed or suggested in either Miller or Loshakove. Withdrawal of the rejection is therefore proper and respectfully requested.

Independent Claim 31

The arguments with respect to claim 1 apply with equal force to claim 31 and the claims dependent thereon. Miller does not disclose a plurality of barbs and a plurality of clips independent of the barbs as set forth in claim 31. Loshakove also does not disclose this combination of elements and no reason to modify Miller to include these features has been provided. Withdrawal of the rejection is therefore proper and respectfully requested.

The claims depending from each of independent claims 17, 22, 28 and 31 are allowable at least by virtue of their dependence upon allowable claims.

CONCLUSION

The amendments made herein are presented solely in an effort to advance prosecution. Applicants reserve all rights to pursue any cancelled subject matter or claims in a subsequent patent application claiming the benefit of priority of the present patent application, and to request rejoinder of any withdrawn claim, as required by MPEP § 821.04.

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If the Examiner believes that a telephone conversation would be useful in addressing any remaining open issues in this case, the Examiner is invited to contact the undersigned at 763-505-8418.

Please charge any required fees including fees for any required extensions of time under 37 C.F.R. §1.17 or credit any overpayment to Deposit Account No. 13-2546.

Respectfully submitted,

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By K. A. Witschen
Katrina A. Witschen
Reg. No. 59,862
MEDTRONIC, INC.
710 Medtronic Parkway
Minneapolis, MN 55432
Tel. 763-505-8418
Fax. 763-505-8436
Customer No. 77218